

North
American

Dräger

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Dräger

June 16, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

RE: Docket No. 98N-0583 - Exports: Notification and Recordkeeping Requirements

Dear Sir or Madam;

The following comments are being made on behalf of North American Dräger in regards to the notice of *Exports: Notification and Recordkeeping Requirements* published in the April 2, 1999 Federal Register (Vol. 64, No. 63 Fed. Reg. pp. 15944-15948). North American Dräger (NAD) is a manufacturer of anesthesia workstations, patient monitors, and operating room data management systems. These comments are offered in regards to recordkeeping requirements and exports to listed countries.

- **Recordkeeping Requirements**

As currently stated in the regulation and as proposed to be maintained for FDA inspection, the exporting company must have records demonstrating that the exported product does not conflict with the laws of the importing country. Further, the requirement states that this should be demonstrated by a letter from an appropriate foreign government agency, and specifically that a letter from nongovernmental bodies or persons is not acceptable (Id. at p. 15948).

This requirement is overly burdensome and often impossible to accomplish. In order to accomplish the requirement for letters from foreign government agency, the FDA has provided a List of Foreign Liaisons. We contend that the list provided is inaccurate and thus makes this requirement difficult, if not impossible. Therefore, the exporting company would be in noncompliance or export not permitted.

As an example of the inaccuracies in the listing, for the Philippines, the Foreign Liaison List provides the contact as: *Director, Department of Health, Bureau of Food and Drugs, Alabang Muntinlupa Metro, Manila, Republic of Philippines*. First, there is neither a telephone or fax number in order to ensure receipt or for direct communication with that office. Second, that office has stated that they are not the authoritative agency to determine importation for medical devices - contrary to the FDA's suggestion. Subsequent contact with another agency in that country has been unproductive.

98N-0583

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SHIP DATE: 16JUN99
ACC# 123733860

ACTUAL WGT: 1 LBS SCALE

TO: DOCKETS MGMT. BRANCH (HFA-305)
FOOD & DRUG ADMINISTRATION
5630 FISHERS LANE, RM. 1061

(301)827-3380

ROCKVILLE

MD 20850

4103 6274 8572

FedEx.

4103 6274 8572

REF: TERESA DORRIETY

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